K130920

SYBRON DENTAL SPECIALTIES

JUL 0 2 2013

510(k) Summary

Submitter:

Sybron Dental Specialties, Inc.
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Wendy Garman - Contact Person

Date Summary Prepared: June 2013

- Trade name – *Correct Plus 1*
- Common name – Impression Material
- Classification name – Material, Impression (21 CFR 872.3660, Product Code ELW)

Devices for Which Substantial Equivalence is Claimed:

- Correct Plus, Class II, K001218, Product Code ELW, Pentron Clinical

Summary

Device Description

Correct Plus 1 impression material (Fast Set) are versatile impression materials designed to accommodate impressions of inlays, crowns and bridges, orthodontic appliances, precision attachments and veneers. The hydrophilic nature of these materials provides outstanding detail in the presence of fluids and exceptional tear strength ensures your detailed impression will remain intact upon removal. *Correct Plus 1* impression material provides multiple packaging options and various set times to accommodate all of your impression needs. For optimal patient acceptance, *Correct Plus 1* impression material is available in unflavored and Berry.

Indications of Use

Correct Plus 1 is a vinyl polysiloxane impression material which is to be used for taking impression of inlays, crowns & bridges, orthodontic appliances, precision attachments and veneers.

Summary of Technological Characteristics Compared to Predicate

Description Information	***Correct Plus 1***	**Correct Plus K001218**
Company Name	Pentron Clinical	Pentron Clinical
Intended Use	*Correct Plus 1* is a vinyl polysiloxane impression material which is to be used for taking impression of inlays, crowns & bridges, orthodontic appliances, precision attachments and veneers.	Correct Plus is a vinyl polysiloxane impression material which is to be used for taking impression of inlays, crowns & bridges, orthodontic appliances, precision attachments and veneers.
Description of Material	Vinly Polysiloxane	Vinyl Polysiloxane
Mode of Use	**Thick n' Thin fast set:** A thixotropic light viscosity wash impression material that is used in two-step heavy-wash or putty-wash procedures to capture accurate subgingival details. **Universal fast set:** A medium viscosity material that produces a highly detailed, extremely accurate monophase impression. It can also be used as an alginate substitute impression material. **Auto-mix Putty fast set:** A heavy viscosity material that provides the hydraulic drive of a hand-mix putty in a convenient auto-mix cartridge. It can be used in all applications putties are used.	**Hydrophilic Light Body:** A thixotropic light viscosity wash impression material that is used in two-step heavy-wash or putty-wash procedures to capture accurate subgingival details. **Hydrophilic Universal:** A medium viscosity material that produces a highly detailed, extremely accurate monophase impression. It can also be used as an alginate substitute impression material. **Putty:** A heavy viscosity material that provides the hydraulic drive of a hand-mix putty in a convenient auto-mix cartridge. It can be used in all applications putties are used.
Principles of Operation	*Correct Plus 1* is a dental impression that takes imprints of hard (teeth) and/or soft tissues. *Correct Plus 1* captures a part or all of a person's dentition and surrounding structures of oral cavity. The dental impression	Correct Plus is a dental impression that takes imprints of hard (teeth) and/or soft tissues. Correct Plus captures a part or all of a person's dentition and surrounding structures of oral cavity. The

Description Information	*Correct Plus 1*	Correct Plus K001218
	forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.	dental impression forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.
Shelf- Life	3 Years	3 Years

Non-Clinical Performance Data

Biocompatibility study was completed, which demonstrates that the material is safe for its intended use. *Correct Plus 1* was tested through the following tests: ISO L929 MEM Elution Test, ISO Kligman Maximization Test and ISO Oral Irritation Test.

The 510(k) submission also includes data from bench testing used to evaluate performance characteristics of *Correct Plus 1* as compare to the predicate device, Correct Plus currently marketed by Pentron Clinical. The characteristics evaluated include Work Time, Oral Set Time, Catalyst Viscosity, Base Viscosity, Out Gassing, Hardness, Mixed Consistency, Dimensional Change, Detail Reproduction, Compatibility with Gypsum, Elastic Recovery, Strain in Compression, Tensile Strength, Tensile Elongation, Tear Strength and Contact Angle.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *Correct Plus 1* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 2, 2013

Sybron Dental Specialties, Incorporated
C/O Ms. Wendy Garman
1717 West Collins Avenue
ORANGE CA 92867

Re: K130920
Trade/Device Name: Correct Plus 1
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: April 1, 2013
Received: April 3, 2013

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130920

Device Name: ***Correct Plus 1***

Indications For Use: *Correct Plus 1* is a vinyl polysiloxane impression material which is to be used for taking impression of inlays, crowns & bridges, orthodontic appliances, precision attachments and veneers.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.06.28 16:56:48 -04'00' for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices